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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/623,200 | 07/18/2003 | Thomas P. Osypka | (49363) 58952 | 2841 |
| 21874 7590 07/16/2007 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205 | | | EXAMINER MULLEN, KRISTEN DROESCH | |
| | | | ART UNIT 3766 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary

Application No.

10/623,200

Applicant(s)

OSYPKA, THOMAS P.

Examiner

Kristen Droesch Mullen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 and 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clemens et al. (2002/0077684) in view of Westlund et al. (2002/0077683).

Regarding claim 1, Clemens shows an elongated lead body having opposed proximal and distal end portions and having a first and second lumen extending therethrough; an electrode assembly (16) operatively associated with the distal end portion of the lead body; a connector assembly (50) operatively associated with the proximal end portion of the lead body, the connector assembly having an engagement stem (54) depending proximally therefrom and the first and second lumens extend through the engagement stem of the connector assembly and including a proximal tip portion and a detachable ported connector fitting (58) having a main body portion (54) and a branch portion (61) which extends from the main branch portion, and the main body portion has an engagement bore at the distal end and a proximal receiving section configured to receive the proximal tip portion of the engagement stem and the main body portion (54) of the ported connector fitting having a primary passageway extending therethrough having at least one passageway (104) extending therethrough to align and communicate with a first lumen (114) and the branch portion (61) of the ported connector fitting having a secondary passageway extending therethrough to align and communicate with a second lumen (104) of the

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lead body through the engagement stem of the connector assembly when the ported connector fitting is engaged with the connector assembly (Figs. 1-2).

Although Clemens shows a connector assembly with an engagement stem (54) and ported connector with an engagement bore, and it isn't clear how they are coupled, Clemens fails to specifically show the engagement stem and engagement bore are threaded. Attention is directed to Westlund who shows a similar connector assembly (860) and ported connector (820) that utilizes threads for coupling the connector assembly and ported connector (Fig. 9). It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ threads on the engagement stem and engagement bore for the coupling of the engagement stem and engagement bore of Clemens wherein so doing would amount to mere substitution of one functional equivalent for another that would work equally well on the Clemens device. MPEP 2144.06, *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982).

Regarding claim 4, Clemens shows at least one passageway formed in the ported connector (58) fitting has a funnel-shaped inlet region (where stylet assembly 62 is introduced), but it unclear as to whether the second passageway in the ported connector fitting (61) also has a funnel shaped inlet region. It would have been an obvious matter of design choice to include a a second funnel shaped inlet region for the second passageway since such a modification would have involved a mere a mere duplication of parts. It has long been held that a mere duplication of parts has no patentable significance unless a new and unexpected result is produced. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

With respect to claims 5-6, Clemens shows a first lumen (114) formed in the lead body has an outlet port at the distal end of the lead body and at a second lumen (104) formed in the

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lead body has an outlet port (102) at a location spaced from the distal end of the lead body (Fig. 2).

Regarding claim 7, Clemens shows the electrode assembly is bipolar and includes a distal tip electrode (16) and a proximal ring electrode (20) (Fig. 2).

With respect to claim 8, Clemens shows a helical conductor coil (138, 140) extending through the lead body for connecting the electrode assembly with the connector assembly (para. [0047]).

Regarding claim 9, Clemens discloses a helical fixation screw operatively associated with the distal end of the lead body for actively securing the lead to cardiac tissue (Col. 7, line 46-51).

With respect to claim 10, Clemens shows a plurality of flexible tines (162) provided at the distal end of the lead body.

The statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art. The designation of one lumen as a guidewire lumen and a second lumen as a fluid delivery lumen has been deemed to be statements of intended use.

Response to Arguments

3. Applicant's arguments filed 4/2/07 have been fully considered but they are not persuasive.
4. In response to applicant's arguments against the references individually (i.e. arguing that Clemens does not show a proximal tip portion and a threaded engagement portion distal to the proximal tip portion and a threaded engaging section distal to the proximal receiving section of the engagement bore and that Westlund does not show a proximal tip portion and a threaded engagement portion distal to the proximal tip portion and a threaded engaging section distal to the proximal receiving section of the engagement bore), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).
5. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "the terminal pin" in the argument that Westlund shows the terminal pin is not threaded) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
6. Applicant appears to argue that Westlund must have a terminal pin for the engagement stem. However, the combination of the terminal pin (860) and locking hub (821) have been interpreted by the examiner to comprise the engagement stem (Fig. 9). As such, since the locking hub of Westlund has threads on it, the engagement stem has threads. Furthermore, the examiner

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believes that the threads are located distally from the proximal tip portion since the proximal tip does not appear to have threads on its outer surface. Westlund further shows the connector fitting (820, 830) has a threaded engaging section that is located distally to the proximal receiving section of the engagement bore, because at least a portion of the threads are located distally from where the terminal pin is located within the bore (Fig. 9). Furthermore, the claim does not require that the engagement bore is sized to receive the entirety of the engagement stem. Westlund shows that a portion of the engagement stem (terminal pin) is received within the bore.

Conclusion

5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Droesch Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

kdm

Kristen Drosch Mullen

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